Notice of Allowability	Application No.	Applicant(s)	
	10/642,970	RITZELER ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed on December 20, 2005*.

2. ☒ The allowed claim(s) is/are *1-5*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Deepak Rao
Primary Examiner
Art Unit: 1624

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Joseph Rossi on March 1, 2006.

The application has been amended as follows:

In claim 1, page 4, lines 18-19 (last two lines of the claim, following the term 'compound', delete " , stereoisomer or mixture of stereoisomers of the compound".

In claim 3, page 7, line 17, delete "ration" and in place insert -- ratio --.

In claim 4, page 8, last line, delete "physiologically tolerated" and in place insert:

-- pharmaceutically acceptable --.

(Copy of the pending claims as amended is enclosed in the Appendix)

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The closest reference of record, US 2003/0119820 teaches indole compounds that are useful as pharmaceutical agents, see the structural formula (I) in page 1. Another reference, U.S. Patent No. 6,358,978 teaches benzimidazole compounds that are useful as pharmaceutical therapeutic agents, see formula I in col. 1. Each of the references require that one of R^1-R^4 is a radical of formula (II) which side chain is structurally distinct from the instant claims. The referenced individually or taken together, do not teach or fairly suggest the instantly claimed compounds and therefore, the instantly claimed compounds are deemed to be novel and patentably distinct.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

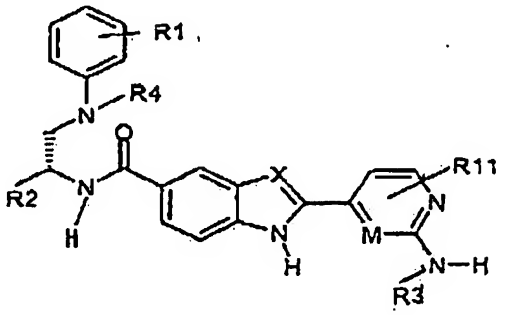
Deepak Rao
Primary Examiner
Art Unit 1624

March 1, 2006

APPENDIX

Listing of Claims:

1. (Currently amended) A compound of the formula I,



(I)

wherein:

X is N or CH;

M is N or CH;

R1 is hydrogen,

halogen chosen from F, Cl, I and Br,

-(C_1-C_4)-alkyl,

-CN,

-CF_3,

-OR^5, wherein R^5 is hydrogen or -(C_1-C_4)-alkyl,

-$N(R^5)$-R^6, wherein R^5 and R^6 are selected from hydrogen and -(C_1-C_4)-alkyl,

-C(O)-R^5, wherein R^5 is hydrogen or -(C_1-C_4)-alkyl, or

-$S(O)_x$-R^5, wherein x is the integer zero, 1 or 2, and wherein R^5 is hydrogen or -(C_1-C_4)-alkyl;

R2 is a heteroaryl radical, which is selected from 3-hydroxypyrro-2,4-dione, imidazole, imidazolidine, imidazoline, indazole, isothiazole, isothiazolidine, isoxazole, 2-isoxazolidine, isoxazolidine, isoxazolone, morpholine, oxazole, 1,3,4-oxadiazole, oxadiazolidinedione, oxadiazolone, 1,2,3,5-oxathiadiazole-2-oxide, 5-oxo-4,5-dihydro[1,3,4]oxadiazole, 5-oxo-1,2,4-thiadiazole, piperazine, pyrazine, pyrazole, pyrazoline, pyrazolidine, pyridazine, pyrimidine, tetrazole, thiadiazole, thiazole, thiomorpholine, triazole and triazolone, wherein the

heteroaryl radical is optionally substituted one, two, or three times by -C(O)-R^5, wherein R^5 is selected from hydrogen and –(C_1-C_4)-alkyl, –(C_1-C_4)-alkyl, -O-R^5, wherein R^5 is selected from hydrogen and –(C_1-C_4)-alkyl, -N(R^5)-R^6, wherein R^5 and R^6 are each selected from hydrogen and –(C_1-C_4-alkyl), halogen, or a keto radical,

-C(O)-OR^5, wherein R^5 is hydrogen or –(C_1-C_4-alkyl), or

-C(O)-N(R^7)-R^8, wherein R^7 and R^8 are each selected from hydrogen, -(C_1-C_4)-alkyl-OH, -O-(C_1-C_4)-alkyl and –(C_1-C_4-alkyl);

R3 is hydrogen or –(C_1-C_4-alkyl);

R4 is a heteroaryl radical, which is selected from pyrrole, furan, thiophene, imidazole, pyrazole, oxazole, isoxazole, thiazole, isothiazole, tetrazole, 1,2,3,5-oxathiadiazole-2-oxides, triazolones, oxadiazolone, isoxazolone, oxadiazolidinedione, triazole, 3-hydroxypyrro-2,4-diones, 5-oxo-1,2,4-thiadiazoles, pyridine, pyrazine, pyrimidine, indole, isoindole, indazole, phthalazine, quinoline, isoquinoline, quinoxaline, quinazoline, cinnoline, β-carboline and benzofused cyclopenta derivatives or cyclohexa derivatives of the heteroaryl radical, wherein the heteroaryl radical is optionally substituted one, two or three times by -(C_1-C_5)-alkyl, -(C_1-C_5)-alkoxy, halogen, nitro, amino, trifluoromethyl, hydroxyl, hydroxy-(C_1-C_4)-alkyl, methylenedioxy, ethylenedioxy, formyl, acetyl, cyano, hydroxycarbonyl, aminocarbonyl or -(C_1-C_4)-alkoxycarbonyl, or

an aryl radical which is selected from phenyl, naphthyl, 1-naphthyl, 2-naphthyl, biphenylyl, 2-biphenylyl, 3-biphenylyl and 4-biphenylyl, anthryl and fluorenyl, wherein the aryl radical is optionally substituted one, two, or three times by –(C_1-C_5)-alkyl, -(C_1-C_5)-alkoxy, halogen, nitro, amino, trifluoromethyl, hydroxyl, hydroxy-(C_1-C_4)-alkyl, methylenedioxy, ethylenedioxy, formyl, acetyl, cyano, hydroxycarbonyl, aminocarbonyl or -(C_1-C_4)-alkoxycarbonyl; and

R11 is hydrogen,

halogen chosen from F, Cl, I and Br,

-(C_1-C_4)-alkyl,

-CN,

-CF_3,

-OR^5, wherein R^5 is hydrogen or -(C_1-C_4)-alkyl,

-$N(R^5)$-R^6, wherein R^5 and R^6 are selected from hydrogen and -(C_1-C_4)-alkyl,

-C(O)-R^5, wherein R^5 is hydrogen or -(C_1-C_4)-alkyl, or

-$S(O)_x$-R^5, wherein x is the integer zero, 1 or 2, and wherein R^5 is hydrogen or -(C_1-C_4)-alkyl,

or a stereoisomer or a mixture of stereoisomers in any ratio of the compound, or a pharmaceutically acceptable salt of the compound~~, stereoisomer or mixture of stereoisomers of the compound~~.

2. (Previously presented) The compound according to claim 1, wherein

X is N or CH;

M is N or CH;

R1 is hydrogen,

halogen chosen from F, Cl, I and Br,

-(C_1-C_4)-alkyl,

-CN,

$-CF_3$,

$-OR^5$, wherein R^5 is hydrogen or $-(C_1-C_4)$-alkyl,

$-N(R^5)-R^6$, wherein R^5 and R^6 are selected from hydrogen and $-(C_1-C_4)$-alkyl,

$-C(O)-R^5$, wherein R^5 is hydrogen or $-(C_1-C_4)$-alkyl, or

$-S(O)_x-R^5$, wherein x is the integer zero, 1 or 2, and wherein R^5 is hydrogen or $-(C_1-C_4)$-alkyl;

R2 is a heteroaryl radical, which is selected from imidazole, isothiazole, isoxazole, 2-isoxazolidine, isoxazolidine, isoxazolone, 1,3,4-oxadiazole, oxadiazolidinedione, 1,2,3,5-oxadiazolone, oxazole, 5-oxo-4,5-dihydro[1,3,4]oxadiazole, tetrazole, thiadiazole, thiazole, triazole and triazolone, wherein the heteroaryl radical is optionally substituted one, two, or three times by a keto radical, F, Cl, I, Br, or $-(C_1-C_2)$-alkyl, or $-C(O)-N(R^7)-R^8$, wherein R^7 and R^8 are each selected from hydrogen, $-(C_1-C_4)$-alkyl-OH, $-O-(C_1-C_4)$-alkyl and $-(C_1-C_4$-alkyl);

R3 is hydrogen, methyl or ethyl;

R4 is a heteroaryl radical which is selected from the group of unsaturated, partially saturated or completely saturated rings which are derived from pyridine, pyrazine, pyrimidine, pyridazine, pyrrole, furan, thiophene, imidazole, pyrazole, oxazole, isoxazole, thiazole, triazole and isothiazole, wherein the heteroaryl radical is optionally substituted one, two or three times by $-(C_1-C_4)$-alkyl, $-(C_1-C_4)$-alkoxy, F, Cl, I, Br, nitro, amino, trifluoromethyl, hydroxyl, hydroxy-(C_1-C_4)-alkyl, methylenedioxy, ethylenedioxy, formyl, acetyl, cyano, hydroxycarbonyl, aminocarbonyl or $-(C_1-C_4)$-alkoxycarbonyl, or phenyl, wherein the phenyl is optionally substituted one, two or three times by F, Cl, I, Br, CF_3, -OH, $-(C_1-C_4)$-alkyl or $-(C_1-C_4)$-alkoxy; and

R11 is hydrogen,

halogen chosen from F, Cl, I and Br,

-(C_1-C_4)-alkyl,

-CN,

-CF_3,

-OR^5, wherein R^5 is hydrogen or -(C_1-C_4)-alkyl,

-$N(R^5)$-R^6, wherein R^5 and R^6 are selected from hydrogen and -(C_1-C_4)-alkyl,

-$C(O)$-R^5, wherein R^5 is hydrogen or -(C_1-C_4)-alkyl, or

-$S(O)_x$-R^5, wherein x is the integer zero, 1 or 2, and wherein R^5 hydrogen or -(C_1-C_4)-alkyl.

3. (Currently amended) The compound according to claim 1, wherein the compound is:

N-[(S)-2-diphenylamino-1-(5-oxo-4,5-dihydro[1,3,4]oxadizol-2-yl)ethyl]-2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carboxamide,

N-{1-carbamoyl-2-[(4-fluorophenyl)pyridin-2-ylamino]ethyl}-2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carboxamide,

N-[(S)-1-(5-oxo-4,5-dihydro-1,3,4-oxadiazol-2-yl)-2-(phenylpyridin-2-ylamino)ethyl]-2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carboxamide,

N-{1-carbamoyl-2-[(4-fluorophenyl)pyridin-2-ylamino]ethyl}-2-(2-aminopyrimidin-4-yl)-1H-indole-5-carboxamide,

N-[2-[(4-fluorophenyl)pyridin-2-ylamino]-1-(4H-[1,2,4]triazol-3-yl)ethyl]-2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carboxamide,

N-[1-carbamoyl-2-(phenylthiazol-2-ylamino)ethyl]-(S)-2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carboxamide,

N-[1-methoxycarbamoyl-2-(phenylpyridin-2-ylamino)ethyl]-(S)-2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carboxamide,

N-{1-carbamoyl-2-[(phenyl)pyridin-2-ylamino]ethyl}-2-(2-aminopyrimidin-4-yl)-1H-indole-5-carboxamide,

N-{1-carbamoyl-2-[(phenyl)pyrimidin-2-ylamino]ethyl}-2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carboxamide,

N-[1-(2-hydroxyethylcarbamoyl)-2-(phenylpyrimidin-2-ylamino)ethyl]-2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carboxamide,

(S)-2-{[2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carbonyl]amino}-3-[phenyl-(4-trifluoromethylpyrimidin-2-yl)amino]propionic acid,

N-{1-carbamoyl-2-[(4-fluorophenyl)-(5-methylpyrimidin-2-yl)amino]ethyl}-2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carboxamide,

N-((S)-1-carbamoyl-2-diphenylaminoethyl)-2-(2-methylaminopyrimidin-4-yl)-1H-benzimidazole-5-carboxamide,

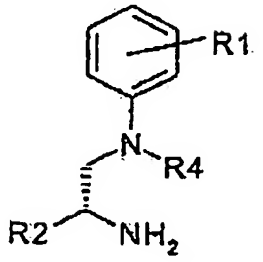
N-{1-carbamoyl-2-[(phenyl)pyrimidin-2-ylamino]ethyl}-2-(2-methylaminopyrimidin-4-yl)-1H-benzimidazole-5-carboxamide, or

N-{1-carbamoyl-2-[(phenyl)pyridin-2-ylamino]ethyl}-2-(2-methylaminopyrimidin-4-yl)-1H-benzimidazole-5-carboxamide,

or a stereoisomer or a mixture of stereoisomers in any ~~ration~~ ratio of the compound, or a pharmaceutically acceptable salt of the compound~~, stereoisomer or mixture of stereoisomers of the compound~~.

4. (Currently amended) A process for preparing a compound according to claim 1, comprising,

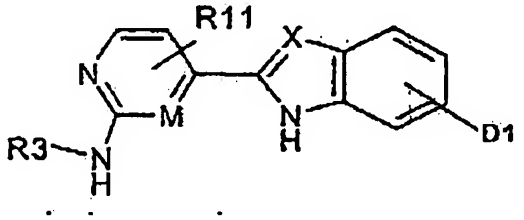
a) reacting a compound of formula IV,



(IV)

wherein R1, R2 and R4 are as defined above,

with an acid chloride or an activated ester of the compound of the formula III,



(III)

wherein D1 is –COOH and R11, X, M and R3 are as defined above, in the presence of a base, or where appropriate, in the presence of a dehydrating agent in solution, and converting the product into a compound of the formula I,

b) separating the compound of the formula I, which has been prepared by method a) and which, on account of its chemical structure, appears in enantiomeric forms, into the pure enantiomers by means of forming salts with enantiomerically pure acids or bases, chromatography on chiral stationary phases or derivatization using chiral enantiomerically pure ~~compounds such as~~ amino acids, separating the resulting diastereomers and eliminating the chiral auxiliary groups, and

c) isolating the compound of the formula I which has been prepared by methods a) or b) in free form, or

d) converting it into ~~physiologically tolerated~~ pharmaceutically acceptable salts when acidic or basic groups are present.

5. (Previously presented) A pharmaceutical composition comprising a pharmaceutically effective amount of the compound according to claim 1 and a pharmaceutically acceptable carrier.

Claims 6 to 14. (Canceled)